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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,801	08/25/2003	Dennis C. Liotta	18085.105233CON1 (EMU 201	2351
20786	7590	12/02/2004	EXAMINER MAIER, LEIGH C	
KING & SPALDING LLP 191 PEACHTREE STREET, N.E. ATLANTA, GA 30303-1763			ART UNIT	PAPER NUMBER

1623

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/647,801

Applicant(s)

LIOTTA ET AL.

Examiner

Leigh C. Maier

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,10,12-16,18-22 and 29-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 1,3,5,10,12-16,18-22 and 29-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/3/04</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1623

DETAILED ACTION

Election/Restrictions

In view of Applicant's response of September 16, 2004, the restriction requirement is withdrawn. Claims 2, 6-9, 11-17, and 22-28 have been canceled. The remaining claims have been amended to comport with the requirements of Group II in the original restriction and election of species requirements. Therefore, all pending claims, including newly added claims 29-71, are under examination.

Information Disclosure Statement

It is noted that many of the references on the PTO-1449 are marked with an asterisk with an illegible notation regarding the designated references. The examiner has reviewed the parent file for the possible presence of these references, but they were not in said file. Therefore, they have been lined through on the form. If Applicant wishes these references to be made of record, it will be necessary to submit these references in response to this Office action.

Claim Rejections - 35 USC § 112 – 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1623

Claims 1, 3, 5, 10, 12-16, 18-22, and 29-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a portion of the genus drawn to compounds having a ceramide-like portion and a glycosyl portion. See, for example, WIEGAND et al (US 5,571,900) at col 1. However, it does not reasonably provide enablement for the full range of compounds defined by the structural formula set forth in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- (1) The quantity of experimentation necessary (time and expense);
- (2) The amount of direction or guidance presented;
- (3) The presence or absence of working examples of the invention;
- (4) The nature of the invention;
- (5) The state of the prior art;
- (6) The relative skill of those in the art;
- (7) The predictability or unpredictability of the art; and
- (8) The breadth of the claims.

The use of glycosphingolipids for the treatment of abnormal cell proliferative disorders is known in the art. For example, AKIMOTO et al (US 5,849,716) teaches a non-overlapping genus of compounds having this utility. See col 1-2. These compounds have a hydrophilic head and what WIEGAND describes as a “double-tailed hydrophobic portion.” Also known are mimetics, such as those taught by FUJITA et al (US 4,880,572), which retain a similar structure. See abstract. Regarding predictability, it would appear likely that the compounds of the instant invention having somewhat analogous structure would also have similar utility—with less predictability as the compounds move farther from this basic structure. However, the genus is very broad and embraces many compounds lacking one or both of the long chain alkyl “tails.”

Art Unit: 1623

The specification provides very little guidance in the way of working examples. At paragraphs [0727]-[0730], the specification demonstrates the efficacy of a single compound. This compound does have the structure described above; however, is not a member of the instant genus. Therefore, it would appear that one of ordinary skill would require an undue amount of experimentation, at great cost to use this invention commensurate with the scope of the claims.

Allowable Subject Matter

Claim 4 appears to be free of the art. Claims 10, 12-16, 21, 22, and 66-71, amended to depend from claim 4 (directly or indirectly), would also appear to be free of the art. AKIMOTO (US 5,849,716) teaches as set forth above. The reference does not teach or fairly suggest the use of the use of the sphingoglycolipid recited in claim 4 for the treatment of proliferative cell disorders.

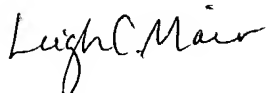
Art Unit: 1623

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier
Patent Examiner
November 19, 2004